Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR 131 - ID : 418731

05/02/2019
SIGNED
Print

Released by s22 on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
55668	E19-517654		Duplicate

ARTG: 280883 Document Container URL

Report Information Section

Enter the ARTG of the device in the search box then press Tab to search for the DIR that this report duplicates. If an ARTG has already been entered below it will be entered in the search field for you.

ARTG Search:	DIR #:
280883	52764 - Distal Protection Filter - Emboli capture guidewire

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	05/02/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
05/02/2019	05/02/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
05/02/2019			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Carer			

Event Description for Website Publication:

s22

Clinical Event Information:

s22

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:
Male	65 kg	56 yrs 3 months

Patient Focused Corrective Action Taken:

Patient History:

Heart problem, diabetes.

Patient Outcome/Consequences:

s22

Additional Event Description:

s22

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Was device directly linked to permanent disabiltiy?:	Other medical devices currently using/implanted:
	Permanent Disability	Yes	

Medical Problem Device Used For: Additional Patients Added:

Blood or metabolism condition 0

Submitting Reporter Section

Search Reporter By Surname: Reporter #: Preferred Contact Method:

Initial Reporter Section

As Above?: *If No, fill out the following:* Initial Reporter Confidential:

No No

Search Reporter By Surname: Initial Reporter #: Preferred Contact Method:

Title: First Name: Surname:

Position: Company/Institution:

Address 1: Address 2: Town/Suburb: State:

Postcode: Country: Phone: Fax:

Australia

Mobile: Email: Allow the device company to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: Search Device ARTG: Device ARTG #: Therapeutic Licence Type:

No 280883 280883 Medical Device

Product Licence Category: Device Class: GMDN / UMDN Code: GMDN / UMDN Text:

Included Class III 44841 Emboli capture guidewire

Brand Name: Initial Device Description: Usage of Device: Software Version:

WIRION EPD System Distal Embolic Protection System Single Use

Model #: Serial #: Batch #: Lot #:

Purchase Date: Expiry Date: Date of Implant: Date of Explant:

25/07/2018

Place of Implantation: Reported Device Location: Access Contact Title: Access Contact First Name:

With Manufacturer

Access Contact Surname: Access Contact Phone: Access Contact Fax: Access Contact Email:

Additional Devices Added:

0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Gardia Medical Ltd		63140	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
			Australia
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Diverse Medical			
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	01/08/2018	s22	
Contact Surname:	**Contact Phone:**		
s22			

Report Information = duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:	
30/09/2016	05/02/2019	Closed	
Problems Observed:			
; ;			

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
No	Yes			Team A (AIMD, III & Reg/Listed)
Report Priority:				
Not Investigated				

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:	
Team Meeting Notes:			

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:	
Meeting Notes:			

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
05/02/2019		Active		30/09/2016
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
			Yes	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**
Yes	Yes	Yes	No	No
Reusable:	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**	**Further Review Needed:**
No				Team Review

Risk Assessment Notes:

Closed duplicate of DIR 52764.

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Final Risk Assessment:

Sponsor/Manufacturer Information Section

s22

Name:		Client #:
Diverse Devices Pty Ltd		62078
Address 1:	**Address 2:**	**Town/Suburb:**
98 Riley Street		Darlinghurst
Postcode:	**Phone:**	**Fax:**
2010	s22	

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:
Additional Details (use for tables):	CAPA# Reference:

Risk Assessment

Frequency:	Severity:
Rating:	

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

06/02/2019 - DIR Closed as a Duplicate of DIR 52764

Click [N] to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		06/02/2019				
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		06/02/2019				

List of Problem Observed Codes - Click [N] to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	Thank you for your report. I am sorry to hear of the event you have experienced. At this stage your report to TGA has been closed for monitoring and trending and forwarded on to the company. The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government. Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme. The TGA conducts a review of all adverse event incidents reported to it. The outcome of the review may take a number of paths including (but not limited to): ▪ The commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes, etc. ▪ The individual report may be closed but used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device. In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate. Should you require further information or clinical assistance related to the use of this medical device and your individual health circumstances, please contact your treating medical professional, hospital or health care service. Assistance and information regarding product refunds, returns or product compensation should be addressed with the Australian Competition and Consumer Commission (ACCC) via https://www.accc.gov.au/consumers/complaints-problems or 1300 302 502. If you would like to lodge a complaint regarding the clinical practice of an Australian healthcare professional you should contact the Australian Health Practitioner Regulation Agency (AHPRA) via https://www.ahpra.gov.au/notifications/make-a-complaint.aspx, or the Health Care Complaints Commission within your State or Territory. More information on the respective State and Territory health complaint organisations can be accessed via https://www.ahpra.gov.au/notifications/further-information/health-complaints-organisations.aspx.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:

Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:

Who sent the device to the TGA?:	Why does the TGA have the sample?:

Additional Patients

Click [N] to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Hospital

How reliant is the affected person on correct/safe operation of this device?: Very

Any other relevant information to aid assessing/investigating the incident?: Yes, medical reports and summaries

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Yes			

Town/Suburb:	State:	Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To

FILE		DIR 55668 - original user report		241	Form

Flow Details : DIR-REQ - Device Incident Request : 160829

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
160829	DIR-REQ		Closed	amandc	OPR Administration User	06/02/2019	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	20/03/2019 12:31:10	
Comment		